Amendments to the Drawings:

The attached sheets of drawings include changes to Figures 3 and 7. These sheets (pages 1-8), which include(s) Figures 1-7, replace the original sheets including Figures 1-7.

Attachment: Replacement Sheet(s)
Annotated Sheet Showing Changes

REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment is respectfully requested. Claims 1-47 were pending in the application; claims 18, 28, 29, 31, 36 and 37 have been amended and claim 30 has been canceled. New claim 48 has been added. No new matter has been added as a result of the claim amendments.

Drawings

The drawings were objected to under 37 CFR §1.83(a). Replacement sheets comprising Figures 1-7, including new Figures 3C, 3D, 7C and 7D, are attached hereto. The new figures are included herein solely for complying with the Examiner's rejection of the Drawings under 37 CFR §1.83(a). Applications assert that the claimed invention is fully disclosed and enabled in the specification as filed.

Figure 3C depicts a double helix stent design and Figure 3D depicts a triple helix stent design. Double and triple helix stent designs were disclosed in the specification in paragraph 0026, as originally filed. Additionally, the terms "double helix" and "triple helix" are well understood by persons of ordinary skill in the art. Therefore no new matter has been introduced by the addition of Figures 3C and 3D.

Figure 7C depicts a stent with two therapeutic coatings separated by a second coating. Figure 7D depicts microspheres disposed a therapeutic coating. Microsphere-containing coatings are disclosed in paragraph 0062 of the specification, as originally filed. Layered therapeutic coatings are disclosed in paragraph 0076 of the specification, as originally filed. Additionally, microsphere-containing coatings and layered coatings are well understood by persons of ordinary skill in the art. Therefore, no new matter has been introduced by the addition of Figures 7C and 7D.

Furthermore, Figure 7A was corrected to include reference to polymer layer 44. Polymer layer 44 was disclosed on page 7 in the unidentified paragraph (between paragraphs 0030 and 0031) and was shown in Figure 7A (unidentified layer). No new matter has been introduced by the correction of Figure 7A.

The specification has been amended to include reference to Figures 3C, 3D, 7C and 7D as shown on page 2 of this paper. Amended figures sheets are attached to this paper as Replacement Sheets.

Claim Objections

Claim 18 has been objected to under 37 CFR §1.75(c) as being in improper form because a dependent claim should refer to a proceeding claim. Claim 18 has been amended to properly depend from claim 17. Claim 18 is now in proper form.

Claim 19 has been objected to under 37 CFR §1.75(c) as being in improper form because a dependent claim shall not refer back to a claim that is held under objection as being in improper form. Claim 18 has been amended to be in proper form and therefore claim 19 is now in proper form.

Therefore, Applicants respectfully request that the objections to claims 18 and 19 be withdrawn.

35 U.S.C. §112 Rejections

Claims 30 and 37 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly our and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 has been cancelled and new claim 48 has been added to more accurately claim application's invention. New claim 48 is dependent on claim 32 which recites "a spray."

Claim 37 has been amended to depend from claim 31 and to recite, in part, "… the coating comprises a polymer selected from the group consisting of…". Furthermore, claim 31 was amended to recite that the coating further comprises a polymer. Therefore there is antecedent basis for "the polymer" in amended claim 37.

Therefore, based on the cancellation of claim 30, addition of new claim 48 and amendments to claims 31 and 37, Applicants respectfully request that the rejection of claim 37 under 35 U.S.C. §112 be withdrawn.

35 U.S.C. §102 Rejections

In order to respond to each of the Examiner's rejections, each basis of rejection, as recited in the Office Action of August 1, 2006 is reproduced below (in italics) along with Applicant's arguments or amendments presented in rebuttal.

A claim is anticipated under 35 U.S.C. §102 only if each and every element as set forth in a claim is found, either expressly or inherently described, in a single prior art reference (MPEP §2131; *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d, 628, 631, 2 USPQ2d 1051 (Fed. Cir. 1987)).

Claims 1-3, 6-12, 17-19, 31, 34-37, 40 and 41 stand rejected under 35 U.S.C. §102(b) as being anticipated by Ragheb et al. (US 6,096,070).

Although the Examiner stated in the introductory sentence on page 5 that claims 1-3, 6-12, 17-19, 34-37, 40 and 41 stand rejected as being anticipated by Ragheb et al., the Examiner additionally provided arguments as to why claims 32, 38, and 43-45 were also anticipated by Ragheb et al. Applicants have addressed all these claims with regard to Ragheb et al.

Ragheb et al. discloses medical devices incorporating drugs or bioactive agents which allow the controlled release of the drug or bioactive agent at a location within the body. Ragheb also discloses a porous layer of a biocompatible polymer applied over the drug or bioactive agent to prevent degradation of the agent. (Column 3, lines 8-26)

"Regarding claim 1, Ragheb et al. discloses a stent (Fig 1 Item 12) locatable interior of an aneurysm site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts and comprises at lease one therapeutic agent (Col 3 Lines 26-39)."

Ragheb does not disclose vascular stents configured for delivery to an aneurysm site. Nor does Ragheb disclose stents which contract when the aneurysmal site contracts. Ragheb discloses and enables bioactive material-releasing stents particularly for preventing abrupt closure and/or restenosis of a blood vessel (column 5 lines 50-51). Ragheb in fact teaches away from a stent which contracts when the aneurysmal site contracts because the disclosed stents are for preventing abrupt closure and/or restenosis of a blood vessel and the stent must therefore exert an outward pressure on the vessel wall to maintain vessel patency, or openness. If the

stents of Ragheb were able to contract when the vessel contracts, the patency maintenance function would be lost, the vessel would close and the stent would be inoperable for its intended purpose, that is, maintaining patency of the vessel.

Therefore Ragheb et al. does not disclose each and every element of independent claim 1 and does not anticipate independent claim 1. Since independent claim 1 is not anticipated by Ragheb et al., claims depending on the non-anticipated claim are also non-anticipated. Therefore, dependent claims 2-41 are also not anticipated by Ragheb et al. However, Applicant will address the rejections of the dependent claims individually for the purposes of completeness of the response.

"Regarding claim 2, Ragheb et al. discloses the stent having a helical configuration (Col 6 Lines 39-42 and Col 15 Line 56)."

On page 9 of the office action, the Examiner states that "[r]egarding claims 4 and 5, Ragheb et al. does not disclose the stent having a helical configuration, the stent comprising at least one helix, the stent comprising two helices, or the stent comprising three helices." Furthermore, since claim 2 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, claim 2 is not anticipated by Ragheb.

"Regarding claim 3, Ragheb et al. discloses the stent comprising at least one helix (Col 6 Lines 39-42 and Col 15 Line 56)."

On page 9 of the office action, the Examiner states that "[r]egarding claims 4 and 5, Ragheb et al. does not disclose the stent having a helical configuration, the stent comprising at least one helix, the stent comprising two helices, or the stent comprising three helices." Furthermore, since claim 3 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, claim 3 is not anticipated by Ragheb.

"Regarding claim 6, Ragheb et al. discloses the stent being self-expandable (Col 6 Line 65)."

Column 6 Lines 64-65 of Ragheb et al. states "...designed to expand to a diameter of about 2 to about 4 mm when so inserted." Ragheb does not disclose self-expanding stents, only stents that are expandable. Stents can be expanded by a variety of means and are not all self-

expanding. Furthermore, since claim 6 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, claim 6 is not anticipated by Ragheb.

"Regarding claim 7, Ragheb et al. discloses the stent comprising a polymer (Col 7 Lines 29-47)."

Claim 7 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 7 is not anticipated by Ragheb.

"Regarding claim 8, Ragheb et al. discloses the polymer being biodegradable (Col 7 Lines 29-47)."

Claim 8 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 8 is not anticipated by Ragheb.

"Regarding claim 9, Ragheb et al. discloses the polymer being cellulose acetate (Col 7 Lines 29-47)."

Claim 9 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 9 is not anticipated by Ragheb.

"Regarding claim 10, Ragheb et al. discloses the therapeutic agent being covalently linked to the polymer (Col 8 Line 25)."

Ragheb et al. disclose binding heparin to "the outer layer of structure 12" (Col 8, lines 25-26). The outermost layer of structure 12 is not the base material. In claim 10 of the instant application, the therapeutic agent is covalently bound to the polymeric intravascular treatment device. Therefore, Ragheb et al. does not disclose all the elements of dependent claim 10. Furthermore, since claim 10 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, claim 10 is not anticipated by Ragheb.

"Regarding claim 11, Ragheb et al. discloses the polymer being not biodegradable (Col 7 Lines 29-47)."

Claim 11 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 11 is not anticipated by Ragheb.

"Regarding claim 12, Ragheb et al. discloses the polymer being polyurethane (Col 7 Lines 29-47)."

Claim 12 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 12 is not anticipated by Ragheb.

"Regarding claim 17, Ragheb et al. discloses the stent comprising metal (Col 7 Lines 29-47)."

Claim 17 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 17 is not anticipated by Ragheb.

"Regarding claim 18, Ragheb et al. discloses the metal alloy being NiTi (Col 7 Lines 29-47)."

Claim 18 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 18 is not anticipated by Ragheb.

"Regarding claim 19, Ragheb et al. discloses the metal being a metal alloy (Col 7 Lines 29-47)."

Claim 19 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 19 is not anticipated by Ragheb.

"Regarding claim 31, Ragheb et al. discloses the therapeutic agent being applied as a coating to the stent (Abstract and Column 7 Lines 55-62)."

Claim 31 has been amended to recite, in part "… said coating further containing a polymer." Ragheb et al. do not disclose coating a medical device with a therapeutic agent in a polymeric coating. Therefore, Ragheb et al. does not disclose all the elements of dependent claim 31. Furthermore, since claim 31 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, claim 31 is not anticipated by Ragheb.

"Regarding claim 32, Ragheb et al. discloses the coating being applied as a film (Col 18 Line 2)."

Claim 32 depends from independent claim 1 and dependent claim 31, neither of which is anticipated by Ragheb et al. as discussed *supra*, therefore claim 32 is not anticipated by Ragheb.

"Regarding claim 34, Ragheb et al. discloses a second coating disposed over the therapeutic coating (Fig. 2 Item 20)."

Claim 34 depends from independent claim 1 and dependent claim 31, neither of which is anticipated by Ragheb et al. as discussed *supra*, therefore claim 34 is not anticipated by Ragheb.

"Regarding claim 35, Ragheb et al. discloses at least two therapeutic coatings, wherein each therapeutic coating is separated by a second coating (Fig. 2 Items 18, 22 and 24)."

Claim 35 depends from independent claim 1 and dependent claim 31, neither of which is anticipated by Ragheb et al. as discussed *supra*, therefore claim 35 is not anticipated by Ragheb.

"Regarding claim 36, Ragheb et al. discloses the coating being a biodegradable coating (Col 9 Lines 20-67)."

Claim 36 has been amended to recite that the coating is a polymeric coating. Ragheb et al. do not disclose coating a medical device with a therapeutic agent in a polymeric coating. Therefore, Ragheb et al. does not disclose all the elements of claim 36. Furthermore, since claim 36 depends from independent claim 1 and dependent claim 31, neither of which is anticipated by Ragheb et al. as discussed *supra*, claim 36 is not anticipated by Ragheb.

"Regarding claim 37, Ragheb et al. discloses the polymer being heparin (Col 9 Line 23)."

Claim 37 depends from independent claim 1 and dependent claim 31, neither of which is anticipated by Ragheb et al. as discussed *supra*, therefore claim 37 is not anticipated by Ragheb.

"Regarding claim 38, Ragheb et al. discloses the coating being a time release coating (Col 10 Lines 30-35)."

Claim 38 depends from independent claim 1 and dependent claim 31, neither of which is anticipated by Ragheb et al. as discussed *supra*, therefore claim 38 is not anticipated by Ragheb.

"Regarding claim 40, Ragheb et al. discloses the stent being formed by laser cutting (Col 16 Line 51)."

Claim 40 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 40 is not anticipated by Ragheb.

"Regarding claim 41, Ragheb et al. discloses the stent being deployed by a catheter (Col 10 Line 63)."

Claim 41 depends from independent claim 1, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 41 is not anticipated by Ragheb.

"Regarding claim 43, Ragheb et al. discloses a helical stent locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts, and comprises at least one therapeutic agent (Col 19 Lines 22-27)."

Ragheb does not disclose vascular stents configured for delivery to an aneurysm site. Nor does Ragheb disclose stents which contract when the aneurysmal site contracts. Ragheb discloses and enables bioactive material-releasing stents particularly for preventing abrupt closure and/or restenosis of a blood vessel (column 5 lines 50-51). Ragheb in fact teaches away from a stent which contracts when the aneurysmal site contracts because the disclosed stents are for preventing abrupt closure and/or restenosis of a blood vessel and the stent must therefore exert an outward pressure on the vessel wall to maintain vessel patency, or openness. If the stents of Ragheb were able to contract when the vessel contracts, the patency maintenance function would be lost, the vessel would close and the stent would be inoperable for its intended purpose, that is, maintaining patency of the vessel.

On page 9 of the office action, the Examiner states that "[r]egarding claims 4 and 5, Ragheb et al. does not disclose the stent having a helical configuration, the stent comprising at least one helix, the stent comprising two helices, or the stent comprising three helices."

Therefore Ragheb et al. does not disclose each and every element of independent claim 43 and does not anticipate independent claim 43. Since independent claim 43 is not anticipated by Ragheb et al., claims depending on the non-anticipated claim are also non-anticipated. Therefore, dependent claims 44 and 45 are also not anticipated by Ragheb et al. However, Applicant will address the rejections of dependent claims 44 and 45 individually for the purposes of completeness of the response.

"Regarding claim 44, Ragheb et al. discloses the stent being biodegradable (Col 7 Lines 29-47)."

Claim 44 depends from independent claim 43, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 44 is not anticipated by Ragheb.

"Regarding claim 45, Ragheb et al. discloses the stent comprises poly(orthoester) biodegradable (Col 7 Lines 29-47)."

Claim 45 depends from independent claim 43, which is not anticipated by Ragheb et al. as discussed *supra*, therefore claim 45 is not anticipated by Ragheb.

Therefore, because each and every element as set forth in the instant claims, namely an intravascular treatment device comprising a stent locatable interior of an aneurysmal site in a blood vessel wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts and comprises at least one therapeutic agent, was not found, either expressly or inherently, in Ragheb et al., the pending claims are not anticipated under 35 USC §102(b). The Examiner is respectfully requested to withdraw the 35 USC §102(b) rejection of pending claims 1-3, 6-12, 17-19, 31, 32, 34-38, 40, and 43-45 over Ragheb et al. in view of Applicants' arguments *supra*.

Claims 1, 31 38 and 39 stand rejected under 35 U.S.C. §102(b) as being anticipated by Hunter et al. (US 5,716,981).

"Hunter discloses coated stents, wherein the coating comprises a polymer and a therapeutic agent (Column 1, Lines 14-16). Hunter also discloses polymers including polytlactic acid and polycaprolactone (column 7); microspheres and size ranges up to approximately 120 microns (figures 5-6, 9-10), and release profiles of the therapeutic agent including about 1% to about 24% of the therapeutic agent released in the first 10 days."

Hunter et al. disclose anti-angiogenic compositions, as well as methods and devices which utilize such compositions for the treatment of cancer and other angiogenesis-dependent diseases (Col 3 Lines 39-42). Hunter et al. also disclose embolizing a blood vessel (Col 4 Line 15). Additionally, Hunter et al. disclose stents having the surface coated with one or more anti-angiogenic compositions and methods for expanding the passageway of a body lumen (Col 4 Lines 21-30).

Hunter does not disclose vascular stents configured for delivery to an aneurysm site. Nor does Hunter disclose stents which contract when the aneurysmal site contracts. Hunter in fact teaches away from a stent which contracts when the aneurysmal site contracts. The stents disclosed in Hunter are for expanding the lumen of a body passageway and in order to

accomplish this function, the stent must exert an outward pressure on the vessel wall to maintain the expanded state. If the stents of Hunter were able to contract when the vessel contracts, this function would be lost, the vessel would close and the stent would be inoperable for its intended purpose, that is, expanding the lumen of the vessel.

Therefore, Hunter et al. do not disclose each and every element of independent claim 1 and does not anticipate independent claim 1. Since independent claim 1 is not anticipated by Hunter et al., claims depending on the non-anticipated claim are also not anticipated. Therefore, dependent claims 31, 38 and 39 are also not anticipated by Hunter et al.

Therefore, because each and every element as set forth in the instant claims, namely an intravascular treatment device comprising a stent locatable interior of an aneurysmal site in a blood vessel wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts and comprises at least one therapeutic agent, was not found, either expressly or inherently, in Hunter et al., the pending claims are not anticipated under 35 USC §102(b). The Examiner is respectfully requested to withdraw the 35 USC §102(b) rejection of pending claims 1, 31, 38 and 39 over Hunter et al. in view of Applicants' arguments *supra*.

Claims 42 and 46 stand rejected under 35 U.S.C. §102(e) as being anticipated by Gerberding (US 6,790,224).

"Gerberding discloses a method of treating an aneurysm comprising deploying the device of claim 1 in an aneurysm site (Fig. 2). Gerberding also discloses deploying a stent graft to exclude the aneurysm the a substantial portion of device of Claim 1 being disposed between the stent graft and the wall of the aneurysm."

Gerberding discloses a medical device comprising an endoprosthesis, such as a stent, having a first end and a second and an expandable sleeve which extends over an end of the endoprosthesis (Col 1 Lines 36-42). The sleeve can include a therapeutic agent (Col 1 Lines 58-59). Gerberding does not disclose incorporating the therapeutic agent into the stent, only into the sleeve. Furthermore, Gerberding does not disclose a vascular stent configured for delivery to an aneurysm site which contracts when the aneurysmal site contracts.

Therefore, because each and every element as set forth in claims 42 and 46, namely an a method of treating an aneurysm comprising deploying a intravascular treatment device in an

aneurysm site wherein the intravascular treatment device comprises a stent locatable interior of an aneurysmal site in a blood vessel wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts and comprises at least one therapeutic agent, was not found, either expressly or inherently, in Gerberding, the pending claims are not anticipated under 35 USC §102(b). The Examiner is respectfully requested to withdraw the 35 USC §102(b) rejection of pending claims 42 and 46 over Gerberding in view of Applicants' arguments *supra*.

35 U.S.C. §103 Rejections

Claims 4 and 5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al. in view of Solem et al. (US 6,210,432); claims 13-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al. in view of Eisert (US 2005/0192664); claims 20-27 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al.; claims 28-30 and 39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al. in view of Sparer et al. (US 2004/0127978); claim 33 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al. in view of Tartaglia et al. (US 5,637,113) and claim 47 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Gerberding in view of Falotico et al. (US 2003/0060877). Applicants respectfully submit that the Examiner has not established *prima facie* obviousness of the pending claims in view of the cited references.

To reject a claim under 35 USC §103(a), the Examiner bears the initial burden of showing an invention to be *prima facie* obvious over the prior art. See *In re Bell*, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1992). If the Examiner cannot establish a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent. See *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed Cir. 1992). The Examiner must meet a three-part test to render a claimed invention *prima facie* obvious.

To begin with, the prior art references cited by the Examiner must provide "motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the application." See *In re Kotzab*, 55 U.S.P.Q.2d 1316 (Fed. Cir. 2000). Where one reference is relied upon by the Examiner, there must be a suggestion or motivation to modify the teachings of that reference. *See id.* Where an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references. See

WMS Gaming Inc. v. International Game Technology, 51 U.S.P.Q.2d 1386 (Fed. Cir. 1999). The suggestion may be found in implicit or explicit teachings within the references themselves, from the ordinary knowledge of one skilled in the art, or from the nature of the problems to be solved. *See id.*

Second, the prior art references cited by the PTO must suggest to one of ordinary skill in the art that the invention would have a reasonable expectation of success. See *In re Dow Chemical*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). The expectation of success, like the motivation to combine two prior art references, must come from the prior art, not the applicant's disclosure. *See id.*

Finally, the Examiner must demonstrate that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims, See *In re Gartside*, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000).

If any one of these three factors is not met, the PTO has failed to establish a *prima facie* case of obviousness and the applicant is entitled to grant of a patent without making any affirmative showing of non-obviousness.

Claims 4 and 5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al. in view of Solem et al. (US 6,210,432).

Ragheb et al. teaches medical devices incorporating drugs or bioactive agents which allow the controlled release of the drug or bioactive agent at a location within the body. Ragheb also teaches a porous layer of a biocompatible polymer applied over the drug or bioactive agent to prevent degradation of the agent. (Column 3, lines 8-26) Ragheb does not teach vascular stents configured for delivery to an aneurysm site. Nor does Ragheb teach stents which contract when the aneurysmal site contracts. Ragheb teaches bioactive material-releasing stents particularly for preventing abrupt closure and/or restenosis of a blood vessel (column 5 lines 50-51).

Solem et al. teaches a device for treatment of mitral insufficiency comprising an elongate body having such dimension as to be insertable into the coronary sinus and having two states; in the first state the elongate body has a shape that is adaptable to the shape of the coronary sinus, and in the second state the elongate body is transferable from the first state to have a reduced

radius of curvature thereby reducing the radius of curvature of the coronary sinus as well as the circumference of the mitral valve annulus.

Solem et al. does not cure the deficiencies of Ragheb et al. Solem et al. does not teach or suggest a helical stent, rather Solem et al. teaches an elongate body which can be comprised of one, two or more metal strings of helical or other shape that are suitable for changing the curvature of the coronary sinus and thereby reduce the circumference of the mitral valve annulus to treat mitral insufficiency. Furthermore, the stent of Ragheb and the elongate body of Solem are not analogous and are intended to solve very different problems. The stent of Ragheb functions to maintain patency of a vessel lumen and the elongate body of Solem is intended to change the curvature of the coronary sinus in order to change the shape of the mitral valve. Therefore, there is no motivation to combine the two references. Additionally, Solem et al. do not teach or suggest a stent that supports an aneurysm site upon deployment and wherein the stent contracts when the aneurysmal site contracts.

Neither of Ragheb et al. or Solem et al., either singly or in combination, teaches or suggests all the limitations of the intravascular treatment device recited in claims 4 and 5 of the instant application. Furthermore, there is no motivation to combine the references as the devices disclosed in Ragheb et al. and in Solem et al. are intended to solve very different problems. Therefore the Examiner cannot establish *prima facie* obviousness of claims 4 and 5. Accordingly, Applicants respectfully submit that claims 4 and 5 are not obvious under 35 USC §103(a) over Ragheb et al. in view of Solem et al. and earnestly request the withdrawal of the outstanding rejection on this basis.

Claims 13-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al. in view of Eisert (US 2005/0192664).

Ragheb et al. teaches medical devices incorporating drugs or bioactive agents which allow the controlled release of the drug or bioactive agent at a location within the body. Ragheb also teaches a porous layer of a biocompatible polymer applied over the drug or bioactive agent to prevent degradation of the agent. (Column 3, lines 8-26) Ragheb does not teach vascular stents configured for delivery to an aneurysm site. Nor does Ragheb teach stents which contract when the aneurysmal site contracts. Ragheb teaches bioactive material-releasing stents

particularly for preventing abrupt closure and/or restenosis of a blood vessel (column 5 lines 50-51).

Eisert does not cure the deficiencies of Ragheb et al. Eisert teaches a stent comprising a pyrimidino-pyrimidine compound to reduce vascular smooth muscle cell proliferation. Eisert teaches a variety of polymers to form a shape-memory polymer member capable of expanding from a contracted state to a stable radially expanded stent when the polymer member is exposed to a selected stimulus (paragraph 0021, emphasis added). Furthermore, Eisert does not teach or suggest a stent that supports an aneurysm site upon deployment and wherein the stent contracts when the aneurysmal site contracts.

Neither of Ragheb et al. or Eisert, either singly or in combination, teaches or suggests all the limitations of the intravascular treatment device recited in claims 13-16 of the instant application, namely a stent implanted at a aneurysm site which contracts when the aneurysmal site contracts. Therefore the Examiner cannot establish *prima facie* obviousness of claims 13-16. Accordingly, Applicants respectfully submit that claims 13-16 are not obvious under 35 USC §103(a) over Ragheb et al. in view of Eisert and earnestly request the withdrawal of the outstanding rejection on this basis.

Claims 20-27 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al.

Ragheb et al. teaches medical devices incorporating drugs or bioactive agents which allow the controlled release of the drug or bioactive agent at a location within the body. Ragheb also teaches a porous layer of a biocompatible polymer applied over the drug or bioactive agent to prevent degradation of the agent. (Column 3, lines 8-26) Ragheb does not teach vascular stents configured for delivery to an aneurysm site. Nor does Ragheb teach stents which contract when the aneurysmal site contracts. Ragheb teaches bioactive material-releasing stents particularly for preventing abrupt closure and/or restenosis of a blood vessel (column 5 lines 50-51).

Therefore Ragheb et al. does not teach or suggest all the limitations of the intravascular treatment device recited in claims 20-27 of the instant application, namely a stent implanted at a aneurysm site which contracts when the aneurysmal site contracts. Therefore the Examiner

cannot establish *prima facie* obviousness of claims 20-27. Accordingly, Applicants respectfully submit that claims 20-27 are not obvious under 35 USC §103(a) over Ragheb et al. and earnestly request the withdrawal of the outstanding rejection on this basis.

Claims 28-30 and 39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al. in view of Sparer et al. (US 2004/0127978).

Ragheb et al. teaches medical devices incorporating drugs or bioactive agents which allow the controlled release of the drug or bioactive agent at a location within the body. Ragheb also teaches a porous layer of a biocompatible polymer applied over the drug or bioactive agent to prevent degradation of the agent. (Column 3, lines 8-26) Ragheb does not teach vascular stents configured for delivery to an aneurysm site. Nor does Ragheb teach stents which contract when the aneurysmal site contracts. Ragheb teaches bioactive material-releasing stents particularly for preventing abrupt closure and/or restenosis of a blood vessel (column 5 lines 50-51).

Sparer et al. does not cure the deficiencies of Ragheb et al. Sparer et al. teaches an active agent delivery system including a blend of at least two miscible polymers and that the miscible polymer blends can form shaped objects (e.g., microspheres, beads, rods, fibers or other shaped objects). Furthermore, Sparer et al. teach that the microspheres are preferably no greater than about 100 microns and that the active agent is released from the coated stent at a rate resulting in at least 10% of the agent being released within 2 days. However, Sparer et al. do not teach or suggest a stent that supports an aneurysm site upon deployment and wherein the stent contracts when the aneurysmal site contracts.

Neither of Ragheb et al. or Sparer et al., either singly or in combination, teach or suggest all the limitations of the intravascular treatment device recited in claims 28-30 and 39 of the instant application, namely a stent implanted at a aneurysm site which contracts when the aneurysmal site contracts. Therefore the Examiner cannot establish *prima facie* obviousness of claims 28-30 and 39. Accordingly, Applicants respectfully submit that claims 28-30 and 39 are not obvious under 35 USC §103(a) over Ragheb et al. in view of Sparer et al. and earnestly request the withdrawal of the outstanding rejection on this basis.

Claim 33 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Ragheb et al. in view of Tartaglia et al. (US 5,637,113).

Ragheb et al. teaches medical devices incorporating drugs or bioactive agents which allow the controlled release of the drug or bioactive agent at a location within the body. Ragheb also teaches a porous layer of a biocompatible polymer applied over the drug or bioactive agent to prevent degradation of the agent. (Column 3, lines 8-26) Ragheb does not teach vascular stents configured for delivery to an aneurysm site. Nor does Ragheb teach stents which contract when the aneurysmal site contracts. Ragheb teaches bioactive material-releasing stents particularly for preventing abrupt closure and/or restenosis of a blood vessel (column 5 lines 50-51).

Tartaglia et al. does not cure the deficiencies of Ragheb et al. Tartaglia et al. teaches a stent wrapped with a polymer film capable of carrying and releasing therapeutic agents. The polymer film of Tartaglia is wrapped on the outside of the stent. As disclosed in Figures 1-4, the stent 20 comprises an expandable stent structural member 22 and a planar sheet or film 24 of polymeric material (Col 4 Lines 16-19). The polymeric sheet or film is not formed on the stent structural member but rather is wrapped around the stent. The stent structural member functions to maintain patentency of the vessel (Col 5 Line 47). However, Tartaglia et al. do not teach or suggest a stent that supports an aneurysm site upon deployment and wherein the stent contracts when the aneurysmal site contracts.

Neither of Ragheb et al. or Tartaglia et al., either singly or in combination, teach or suggest all the limitations of the intravascular treatment device recited in claim 33 of the instant application, namely a stent implanted at a aneurysm site which contracts when the aneurysmal site contracts. Therefore the Examiner cannot establish *prima facie* obviousness of claim 33. Accordingly, Applicants respectfully submit that claim 33 is not obvious under 35 USC §103(a) over Ragheb et al. in view of Tartaglia et al. and earnestly request the withdrawal of the outstanding rejection on this basis.

Claim 47 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Gerberding in view of Falotico et al. (US 2003/0060877).

Gerberding teaches a medical device comprising an endoprosthesis, such as a stent, having a first end and a second and an expandable sleeve which extends over an end of the endoprosthesis (Col 1 Lines 36-42). The sleeve can include a therapeutic agent (Col 1 Lines 58-59). Gerberding does not teach or suggest incorporating the therapeutic agent into the stent, only into the sleeve. Furthermore, Gerberding does not teach or suggest a vascular stent that supports an aneurysm site upon deployment and wherein the stent contracts when the aneurysmal site contracts.

Falotico et al. teaches medical devices for the treatment of vascular disease wherein the medical device incorporates one or more drugs, agents or compounds. Falotico further teaches incorporating pro-drugs into the medical devices. Falotico defines the claimed medical device as comprising "a scaffold structure for maintaining luminal patency" (paragraph 0030). However, Falotico et al. do not teach or suggest a stent that supports an aneurysm site upon deployment and wherein the stent contracts when the aneurysmal site contracts.

Neither of Ragheb et al. or Falotico et al., either singly or in combination, teach or suggest all the limitations of the intravascular treatment device recited in claim 47 of the instant application, namely a stent implanted at a aneurysm site which contracts when the aneurysmal site contracts. Therefore the Examiner cannot establish *prima facie* obviousness of claim 47. Accordingly, Applicants respectfully submit that claim 47 is not obvious under 35 USC §103(a) over Ragheb et al. in view of Falotico et al. and earnestly request the withdrawal of the outstanding rejection on this basis.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 566-1888.

Respectfully submitted,

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